

Rejection of Claims 19, 20, 25 and 35
Under 35 U.S.C. §112, Second Paragraph

Claims 19, 20, 25 and 35 stand rejected under §112, second paragraph. Applicants respectfully overcome the claim by claim basis of this rejection as follows:

Claim 19 - claim 19 has been amended to more clearly recite an epitope as being an epitope of an expressed gene product, not of the gene itself.

Claim 20 - claim 20 has been amended in a similar fashion to claim 19, so as to also recite an epitope as being an epitope of an expressed gene product, not of the gene itself.

Claim 25 - claim 25 has been amended to correct the problem regarding a "clear and positive prior antecedent basis" for the term mammal.

Claim 35 - claim 35 has been amended to more precisely recite in step f) the presence of a transcription termination sequence downstream of the most 3' open reading frame.

Applicants respectfully take the position that this rejection is overcome by amendment to claims 19, 20, 25, and 35. Applicants respectfully take the position that these claims are now in proper form for allowance, along with previously allowed claims 1, 5-18, 21, 22, 39-41, 44, 45, 48 and 49. Early action to that end is earnestly solicited. The Examiner is invited to contact the undersigned attorney if clarification is required on any aspect of this response, or if any of the claims are considered to require further amendment to be placed in condition for allowance after entry of this Rule 116, Amendment under Final.

Respectfully submitted,

Date: OCTOBER 31, 2007

By: J. Mark Hand
J. Mark Hand
Reg. No. 36,545
Attorney for Applicant
Merck & Co., Inc. P.O. Box 2000
Rahway, NJ 07065-0907
(732) 594-3905

MARKED-UP VERSION OF APPLICATION AS AMENDED HEREIN

IN THE CLAIMS:

Claims 19, 20, 25, 35, and 48 were amended as follows:

Please amend claim 19, with the clean version provided below to read as follows:

19(Amended). The polynucleotide of Claim 18 wherein the HIV immunogenic epitope [is selected] of step b) is a gene product expressed from an HIV gene selected from the group of HIV genes consisting of gag, gag-protease, and env or an immunogenic subportion thereof; the cytokine is interleukin-12, and the T-cell costimulatory element is a B7 protein

Please amend claim 20, with the clean version provided below to read as follows:

20(Amended) The polynucleotide of Claim 19 wherein the env immunogenic epitope is a gene product expressed from an env open reading frame selected from the group consisting of HIV gp160, HIV gp120 and HIV gp41.

Please amend claim 25, with the clean version provided below to read as follows:

25(Amended). A method for co-expression in a single cell *in vivo*, of at least two gene products, which comprises introducing between about 1 ng and about 100 mg of the polynucleotide of Claim 1 into the tissue of [the] a mammal.

Please amend claim 35, with the clean version provided below to read as follows:

35(Three Times Amended). A polynucleotide which is non-replicating in eukaryotic cells *in vivo*, comprising:
a) a eukaryotic transcriptional promoter;
b) an open reading frame 3' to the transcriptional promoter encoding an immunogenic HIV epitope wherein the open reading frame has a splice donor sequence at the 5'-side of the open reading frame, a REV responsive element anywhere within the open reading frame, and a stop codon encoding the termination of translation of the open reading frame;

- c) an internal ribosome entry site (IRES) 3' to the translation stop codon of the open reading frame;
- d) an open reading frame encoding a spliced HIV REV gene at the 3' end of which is a translation stop codon;
- e) optionally, 3' to the REV translation stop codon, a second IRES, followed by an open reading frame encoding immunomodulatory or immunostimulatory genes being selected from the group consisting of GM-CSF, IL-12, interferon, and a B7 protein; and,
- f) a transcription-termination signal 3' of the most downstream open reading frame of step d) or optionally, step [f] e).

Please amend claim 48, with the clean version provided below to read as follows:

48(New). The polynucleotide of Claim [12] 1 wherein the first cistron contains an HIV *gag* gene or portion thereof which encodes a *gag* immunogenic epitope, the second cistron encodes a cytokine, and the third cistron encodes a T-cell costimulatory element, wherein the first, second and third cistron may be presented in any combination.